

(1) Resident rights (§ 483.10(b)(3) through (b)(6), (d), (e), (h), (i), (j)(1) (vii) and (viii), (l), and (m) of this chapter).

(2) Admission, transfer, and discharge rights (§ 483.12(a) of this chapter).

(3) Resident behavior and facility practices (§ 483.13 of this chapter).

(4) Patient activities (§ 483.15(f) of this chapter), except that the services may be directed either by a qualified professional meeting the requirements of § 485.15(f)(2), or by an individual on the facility staff who is designated as the activities director and who serves in consultation with a therapeutic recreation specialist, occupational therapist, or other professional with experience or education in recreational therapy.

(5) Social services (§ 483.15(g) of this chapter).

(6) Comprehensive assessment, comprehensive care plan, and discharge planning (§ 483.20(b), (d), and (e) of this chapter).

(7) Specialized rehabilitative services (§ 483.45 of this chapter).

(8) Dental services (§ 483.55 of this chapter).

(9) Nutrition (§ 483.25(i) of this chapter).

[58 FR 30671, May 26, 1993, as amended at 60 FR 45851, Sept. 1, 1995; 62 FR 46036, 46037, Aug. 29, 1997]

### Subpart G—[Reserved]

### Subpart H—Conditions of Participation for Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services

#### § 485.701 Basis and scope.

This subpart implements section 1861(p)(4) of the Act, which—

(a) Defines outpatient physical therapy and speech pathology services;

(b) Imposes requirements with respect to adequate program, facilities, policies, staffing, and clinical records; and

(c) Authorizes the Secretary to establish by regulation other health and safety requirements.

[60 FR 2327, Jan. 9, 1995]

#### § 485.703 Definitions.

*Clinic.* A facility that is established primarily to furnish outpatient physician services and that meets the following tests of physician involvement:

(1) The medical services are furnished by a group of three or more physicians practicing medicine together.

(2) A physician is present during all hours of operation of the clinic to furnish medical services, as distinguished from purely administrative services.

*Organization.* A clinic, rehabilitation agency, or public health agency.

*Public health agency.* An official agency established by a State or local government, the primary function of which is to maintain the health of the population served by performing environmental health services, preventive medical services, and in certain cases, therapeutic services.

*Rehabilitation agency.* An agency that—

(1) Provides an integrated multidisciplinary rehabilitation program designed to upgrade the physical functioning of handicapped disabled individuals by bringing specialized rehabilitation staff together to perform as a team; and

(2) Provides at least the following services:

(i) Physical therapy or speech-language pathology services.

(ii) Social or vocational adjustment services.

*Supervision.* Authoritative procedural guidance that is for the accomplishment of a function or activity and that—

(1) Includes initial direction and periodic observation of the actual performance of the function or activity; and

(2) Is furnished by a qualified person—

(i) Whose sphere of competence encompasses the particular function or activity; and

(ii) Who (unless otherwise provided in this subpart) is on the premises if the person performing the function or activity does not meet the assistant-level

practitioner qualifications specified in § 485.705.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 53 FR 12015, Apr. 12, 1988; 54 FR 38679, Sept. 20, 1989. Redesignated and amended at 60 FR 2326, 2327, Jan. 9, 1995; 60 FR 50447, Sept. 29, 1995.]

**§ 485.705 Personnel qualifications.**

The training, experience, and membership requirements for personnel involved in the furnishing of outpatient physical therapy and speech-language pathology services are as follows:

(a) *Administrator*. A person who has a bachelor's degree and:

(1) Has experience or specialized training in the administration of health institutions or agencies; or

(2) Is qualified and has experience in one of the professional health disciplines.

(b) *Physical therapist*. A person who is licensed as a physical therapist by the State in which he or she is practicing if the State licenses physical therapists. and—

(1) Has graduated from a physical therapy curriculum approved by the American Physical Therapy Association, or by the Council on Medical Education and Hospitals of the American Medical Association, or jointly by the Council on Medical Education of the American Medical Association and the American Physical Therapy Association; or

(2) Prior to January 1, 1966:

(i) Was admitted to membership by the American Physical Therapy Association; or

(ii) Was admitted to registration by the American Registry of Physical Therapists; or

(iii) Has graduated from a physical therapy curriculum in a 4-year college or university approved by a State department of education; or

(3) Has 2 years of appropriate experience as a physical therapist and has achieved a satisfactory grade on a proficiency examination approved by the Secretary, except that such determinations of proficiency shall not apply with respect to persons initially licensed by a State after December 31, 1977, or seeking qualification as a physical therapist after such date; or

(4)(i) Was licensed or registered prior to January 1, 1966, and

(ii) Prior to January 1, 1970, had 15 years of full-time experience in the treatment of illness or injury through the practice of physical therapy in which services were rendered under the order and direction of attending and referring doctors of medicine or osteopathy; or

(5) If trained outside the United States:

(i) Was graduated since 1928 from a physical therapy curriculum approved in the country in which the curriculum was located and in which there is a member organization of the World Confederation for Physical Therapy.

(ii) Meets the requirements for membership in a member organization of the World Confederation for Physical Therapy.

(iii) Has 1 year of experience under the supervision of an active member of the American Physical Therapy Association, and

(iv) Has successfully completed a qualifying examination as prescribed by the American Physical Therapy Association.

(c) *Physical therapist assistant*. A person who is licensed as a physical therapist assistant by the State in which he is practicing, if the State licenses such assistants, and has graduated from a 2-year college-level program approved by the American Physical Therapy Association.

(d) *Physician*. A person who is—

(1) A doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he or she performs those functions or actions; or

(2) A doctor of podiatric medicine, but only with respect to the functions which he or she is legally authorized to perform by the State in which he or she performs them.

(e) *Psychologist*. A person who:

(1) Holds a doctoral degree in psychology from a training program approved by the American Psychological Association; or

(2) Has attained certification or licensing by the State, or non-statutory certification by the State psychological association.

(f) *Social worker.* A person who is licensed by the State in which he is practicing if the State licenses social workers, is a graduate of a school of social work accredited or approved by the Council on Social Work Education, and has 1 year of social work experience in a health-care setting.

(g) *Speech pathologist.* A person who is licensed by the State in which he is practicing, if the State licenses speech pathologists, and

(1) Is eligible for a certificate of clinical competence in speech pathology granted by the American Speech and Hearing Association under its requirements in effect on January 17, 1974; or

(2) Meets the educational requirements for certification, and is in the process of accumulating the supervised clinical experience required for certification.

(h) *Vocational specialist.* A person who has a baccalaureate degree and:

(1) Two years experience in vocational counseling in a rehabilitation setting such as a sheltered workshop, State employment service agency, etc.; or

(2) At least 18 semester hours in vocational rehabilitation, educational or vocational guidance, psychology, social work, special education or personnel administration, and 1 year of experience in vocational counseling in a rehabilitation setting; or

(3) A master's degree in vocational counseling.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 53 FR 12015, Apr. 12, 1988; 54 FR 38679, Sept. 20, 1989. Redesignated and amended at 60 FR 2326, 2327, Jan. 9, 1995]

**§ 485.707 Condition of participation: Compliance with Federal, State, and local laws.**

The organization and its staff are in compliance with all applicable Federal, State, and local laws and regulations.

(a) *Standard: Licensure of organization.* In any State in which State or applicable local law provides for the licensing of organizations, a clinic, rehabilitation agency, or public health agency is licensed in accordance with applicable laws.

(b) *Standard: Licensure or registration of personnel.* Staff of the organization

are licensed or registered in accordance with applicable laws.

[41 FR 20865, May 21, 1976, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326, 2327, Jan. 9, 1995]

**§ 485.709 Condition of participation: Administrative management.**

The clinic or rehabilitation agency has an effective governing body that is legally responsible for the conduct of the clinic or rehabilitation agency. The governing body designates an administrator, and establishes administrative policies.

(a) *Standard: Governing body.* There is a governing body (or designated person(s) so functioning) which assumes full legal responsibility for the overall conduct of the clinic or rehabilitation agency and for compliance with applicable laws and regulations. The name of the owner(s) of the clinic or rehabilitation agency is fully disclosed to the State agency. In the case of corporations, the names of the corporate officers are made known.

(b) *Standard: Administrator.* The governing body—

(1) Appoints a qualified full-time administrator;

(2) Delegates to the administrator the internal operation of the clinic or rehabilitation agency in accordance with written policies;

(3) Defines clearly the administrator's responsibilities for procurement and direction of personnel; and

(4) Designates a competent individual to act during temporary absence of the administrator.

(c) *Standard: Personnel policies.* Personnel practices are supported by appropriate written personnel policies that are kept current. Personnel records include the qualifications of all professional and assistant level personnel, as well as evidence of State licensure if applicable.

(d) *Standard: Patient care policies.* Patient care practices and procedures are supported by written policies established by a group of professional personnel including one or more physicians associated with the clinic or rehabilitation agency, one or more qualified physical therapists (if physical therapy services are provided), and one

or more qualified speech pathologists (if speech pathology services are provided). The policies govern the outpatient physical therapy and/or speech pathology services and related services that are provided. These policies are evaluated at least annually by the group of professional personnel, and revised as necessary based upon this evaluation.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 53 FR 12015, Apr. 12, 1988. Redesignated and amended at 60 FR 2326, 2327, Jan. 9, 1995; 60 FR 50447, Sept. 29, 1995]

**§485.711 Condition of participation: Plan of care and physician involvement.**

For each patient in need of outpatient physical therapy or speech pathology services there is a written plan of care established and periodically reviewed by a physician, or by a physical therapist or speech pathologist respectively. The organization has a physician available to furnish necessary medical care in case of emergency.

(a) *Standard: Medical history and prior treatment.* The following are obtained by the organization before or at the time of initiation of treatment:

- (1) The patient's significant past history.
- (2) Current medical findings, if any.
- (3) Diagnosis(es), if established.
- (4) Physician's orders, if any.
- (5) Rehabilitation goals, if determined.
- (6) Contraindications, if any.
- (7) The extent to which the patient is aware of the diagnosis(es) and prognosis.
- (8) If appropriate, the summary of treatment furnished and results achieved during previous periods of rehabilitation services or institutionalization.

(b) *Standard: Plan of care.* (1) For each patient there is a written plan of care established by the physician or by the physical therapist or speech-language pathologist who furnishes the services.

(2) The plan of care for physical therapy or speech pathology services indicates anticipated goals and specifies for those services the—

- (i) Type;
- (ii) Amount;

(iii) Frequency; and

(iv) Duration.

(3) The plan of care and results of treatment are reviewed by the physician or by the individual who established the plan at least as often as the patient's condition requires, and the indicated action is taken. (For Medicare patients, the plan must be reviewed by a physician at least every 30 days in accordance with §410.61(e) of this chapter.)

(4) Changes in the plan of care are noted in the clinical record. If the patient has an attending physician, the therapist or speech-language pathologist who furnishes the services promptly notifies him or her of any change in the patient's condition or in the plan of care.

(c) *Standard: Emergency care.* The organization provides for one or more doctors of medicine or osteopathy to be available on call to furnish necessary medical care in case of emergency. The established procedures to be followed by personnel in an emergency cover immediate care of the patient, persons to be notified, and reports to be prepared.

[54 FR 38679, Sept. 20, 1989. Redesignated and amended at 60 FR 2326, 2327, Jan. 9, 1995]

**§485.713 Condition of participation: Physical therapy services.**

If the organization offers physical therapy services, it provides an adequate program of physical therapy and has an adequate number of qualified personnel and the equipment necessary to carry out its program and to fulfill its objectives.

(a) *Standard: Adequate program.* (1) The organization is considered to have an adequate outpatient physical therapy program if it can:

- (i) Provide services using therapeutic exercise and the modalities of heat, cold, water, and electricity;
- (ii) Conduct patient evaluations; and
- (iii) Administer tests and measurements of strength, balance, endurance, range of motion, and activities of daily living.

(2) A qualified physical therapist is present or readily available to offer supervision when a physical therapist assistant furnishes services.

(1) If a qualified physical therapist is not on the premises during all hours of operation, patients are scheduled so as to ensure that the therapist is present when special skills are needed, for example, for evaluation and reevaluation.

(ii) When a physical therapist assistant furnishes services off the organization's premises, those services are supervised by a qualified physical therapist who makes an onsite supervisory visit at least once every 30 days.

(b) *Standard: Facilities and equipment.* The organization has the equipment and facilities required to provide the range of services necessary in the treatment of the types of disabilities it accepts for service.

(c) *Standard: Personnel qualified to provide physical therapy services.* Physical therapy services are provided by, or under the supervision of, a qualified physical therapist. The number of qualified physical therapists and qualified physical therapist assistants is adequate for the volume and diversity of physical therapy services offered. A qualified physical therapist is on the premises or readily available during the operating hours of the organization.

(d) *Standard: Supportive personnel.* If personnel are available to assist qualified physical therapists by performing services incident to physical therapy that do not require professional knowledge and skill, these personnel are instructed in appropriate patient care services by qualified physical therapists who retain responsibility for the treatment prescribed by the attending physician.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326, 2327, Jan. 9, 1995; 60 FR 50447, Sept. 29, 1995]

#### §485.715 Condition of participation: Speech pathology services.

If speech pathology services are offered, the organization provides an adequate program of speech pathology and has an adequate number of qualified personnel and the equipment necessary to carry out its program and to fulfill its objectives.

(a) *Standard: Adequate program.* The organization is considered to have an adequate outpatient speech pathology

program if it can provide the diagnostic and treatment services to effectively treat speech disorders.

(b) *Standard: Facilities and equipment.* The organization has the equipment and facilities required to provide the range of services necessary in the treatment of the types of speech disorders it accepts for service.

(c) *Standard: Personnel qualified to provide speech pathology services.* Speech pathology services are given or supervised by a qualified speech pathologist and the number of qualified speech pathologists is adequate for the volume and diversity of speech pathology services offered. At least one qualified speech pathologist is present at all times when speech pathology services are furnished.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326-2328, Jan. 9, 1995]

#### §485.717 Condition of participation: Rehabilitation program.

This condition and its standards apply only to a rehabilitation agency's own patients, not to patients of hospitals, skilled nursing facilities (SNFs), or Medicaid nursing facilities (NFs) to whom the agency furnishes services. (The hospital, SNF, or NF is responsible for ensuring that qualified staff furnish services for which they arrange or contract for their patients.) The rehabilitation agency provides, in addition to physical therapy and speech-language pathology services, social or vocational adjustment services to all of its patients who need them. The agency provides for special qualified staff to evaluate the social and vocational factors, to counsel and advise on the social or vocational problems that arise from the patient's illness or injury, and to make appropriate referrals for needed services.

(a) *Standard: Qualification of staff.* The agency's social or vocational adjustment services are furnished as appropriate, by qualified psychologists, qualified social workers, or qualified vocational specialists. Social or vocational adjustment services may be performed by a qualified psychologist or qualified social worker. Vocational adjustment services may be furnished by a qualified vocational specialist.

(b) *Standard: Arrangements for social or vocational adjustment services.* (1) If a rehabilitation agency does not provide social or vocational adjustment services through salaried employees, it may provide those services through a written contract with others who meet the requirements and responsibilities set forth in this subpart for salaried personnel.

(2) The contract must specify the term of the contract and the manner of termination or renewal and provide that the agency retains responsibility for the control and supervision of the services.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 56 FR 46562, Sept. 13, 1991. Redesignated and amended at 60 FR 2326, 2328, Jan. 9, 1995; 60 FR 11632, Mar. 2, 1995; 60 FR 50447, Sept. 29, 1995]

**§ 485.719 Condition of participation: Arrangements for physical therapy and speech pathology services to be performed by other than salaried organization personnel.**

(a) *Conditions.* If an organization provides outpatient physical therapy or speech pathology services under an arrangement with others, the services are to be furnished in accordance with the terms of a written contract, which provides that the organization retains of professional and administrative responsibility for, and control and supervision of, the services.

(b) *Standard: Contract provisions.* The contract—

(1) Specifies the term of the contract and the manner of termination or renewal;

(2) Requires that personnel who furnish the services meet the requirements that are set forth in this subpart for salaried personnel; and

(3) Provides that the contracting outside resource may not bill the patient or Medicare for the services. This limitation is based on section 1861(w)(1) of the Act, which provides that—

(i) Only the provider may bill the beneficiary for covered services furnished under arrangements; and

(ii) Receipt of Medicare payment by the provider, on behalf of an entitled individual, discharges the liability of

the individual or any other person to pay for those services.

[56 FR 46562, Sept. 13, 1991. Redesignated and amended at 60 FR 2326, 2328, Jan. 9, 1995; 60 FR 50447, Sept. 29, 1995]

**§ 485.721 Condition of participation: Clinical records.**

The organization maintains clinical records on all patients in accordance with accepted professional standards, and practices. The clinical records are completely and accurately documented, readily accessible, and systematically organized to facilitate retrieving and compiling information.

(a) *Standard: Protection of clinical record information.* The organization recognizes the confidentiality of clinical record information and provides safeguards against loss, destruction, or unauthorized use. Written procedures govern the use and removal of records and the conditions for release of information. The patient's written consent is required for release of information not authorized by law.

(b) *Standard: Content.* The clinical record contains sufficient information to identify the patient clearly, to justify the diagnosis(es) and treatment, and to document the results accurately. All clinical records contain the following general categories of data:

(1) Documented evidence of the assessment of the needs of the patient, of an appropriate plan of care, and of the care and services furnished.

(2) Identification data and consent forms.

(3) Medical history.

(4) Report of physical examinations, if any.

(5) Observations and progress notes.

(6) Reports of treatments and clinical findings.

(7) Discharge summary including final diagnosis(es) and prognosis.

(c) *Standard: Completion of records and centralization of reports.* Current clinical records and those of discharged patients are completed promptly. All clinical information pertaining to a patient is centralized in the patient's clinical record. Each physician signs the entries that he or she makes in the clinical record.

(d) *Standard: Retention and preservation.* Clinical records are retained for at least:

(1) The period determined by the respective State statute, or the statute of limitations in the State; or

(2) In the absence of a State statute—

(i) Five years after the date of discharge; or

(ii) In the case of a minor, 3 years after the patient becomes of age under State law or 5 years after the date of discharge, whichever is longer.

(e) *Standard: Indexes.* Clinical records are indexed at least according to name of patient to facilitate acquisition of statistical medical information and retrieval of records for research or administrative action.

(f) *Standard: Location and facilities.* The organization maintains adequate facilities and equipment, conveniently located, to provide efficient processing of clinical records (reviewing, indexing, filing, and prompt retrieval).

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326-2328, Jan. 9, 1995]

#### § 485.723 Condition of participation: Physical environment.

The building housing the organization is constructed, equipped, and maintained to protect the health and safety of patients, personnel, and the public and provides a functional, sanitary, and comfortable environment.

(a) *Standard: Safety of patients.* The organization satisfies the following requirements:

(1) It complies with all applicable State and local building, fire, and safety codes.

(2) Permanently attached automatic fire-extinguishing systems of adequate capacity are installed in all areas of the premises considered to have special fire hazards. Fire extinguishers are conveniently located on each floor of the premises. Fire regulations are prominently posted.

(3) Doorways, passageways and stairwells negotiated by patients are:

(i) Of adequate width to allow for easy movement of all patients (including those on stretchers or in wheelchairs), (ii) free from obstruction at all

times, and (iii) in the case of stairwells, equipped with firmly attached handrails on at least one side.

(4) Lights are placed at exits and in corridors used by patients and are supported by an emergency power source.

(5) A fire alarm system with local alarm capability and, where applicable, an emergency power source, is functional.

(6) At least two persons are on duty on the premises of the organization whenever a patient is being treated.

(7) No occupancies or activities undesirable or injurious to the health and safety of patients are located in the building.

(b) *Standard: Maintenance of equipment, building, and grounds.* The organization establishes a written preventive-maintenance program to ensure that—

(1) The equipment is operative, and is properly calibrated; and

(2) The interior and exterior of the building are clean and orderly and maintained free of any defects that are a potential hazard to patients, personnel, and the public.

(c) *Standard: Other environmental considerations.* The organization provides a functional, sanitary, and comfortable environment for patients, personnel, and the public.

(1) Provision is made for adequate and comfortable lighting levels in all areas; limitation of sounds at comfort levels; a comfortable room temperature; and adequate ventilation through windows, mechanical means, or a combination of both.

(2) Toilet rooms, toilet stalls, and lavatories are accessible and constructed so as to allow use by non-ambulatory and semiambulatory individuals.

(3) Whatever the size of the building, there is an adequate amount of space for the services provided and disabilities treated, including reception area, staff space, examining room, treatment areas, and storage.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326-2328, Jan. 9, 1995]



**§ 485.725 Condition of participation:  
Infection control.**

The organization that provides outpatient physical therapy services establishes an infection-control committee of representative professional staff with responsibility for overall infection control. All necessary housekeeping and maintenance services are provided to maintain a sanitary and comfortable environment and to help prevent the development and transmission of infection.

(a) *Standard: Infection-control committee.* The infection-control committee establishes policies and procedures for investigating, controlling, and preventing infections in the organization and monitors staff performance to ensure that the policies and procedures are executed.

(b) All personnel follow written procedures for effective aseptic techniques. The procedures are reviewed annually and revised if necessary to improve them.

(c) *Standard: Housekeeping.* (1) The organization employs sufficient housekeeping personnel and provides all necessary equipment to maintain a safe, clean, and orderly interior. A full-time employee is designated as the one responsible for the housekeeping services and for supervision and training of housekeeping personnel.

(2) An organization that has a contract with an outside resource for housekeeping services may be found to be in compliance with this standard provided the organization or outside resource or both meet the requirements of the standard.

(d) *Standard: Linen.* The organization has available at all times a quantity of linen essential for proper care and comfort of patients. Linens are handled, stored, processed, and transported in such a manner as to prevent the spread of infection.

(e) *Standard: Pest control.* The organization's premises are maintained free from insects and rodents through operation of a pest-control program.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326, 2328, Jan. 9, 1995; 60 FR 50447, Sept. 29, 1995]

**§ 485.727 Condition of participation:  
Disaster preparedness.**

The organization has a written plan, periodically rehearsed, with procedures to be followed in the event of an internal or external disaster and for the care of casualties (patients and personnel) arising from a disaster.

(a) *Standard: Disaster plan.* The organization has a written plan in operation, with procedures to be followed in the event of fire, explosion, or other disaster. The plan is developed and maintained with the assistance of qualified fire, safety, and other appropriate experts, and includes:

- (1) Transfer of casualties and records;
- (2) The location and use of alarm systems and signals;
- (3) Methods of containing fire;
- (4) Notification of appropriate persons; and
- (5) Evacuation routes and procedures.

(b) *Standard: Staff training and drills.* All employees are trained, as part of their employment orientation, in all aspects of preparedness for any disaster. The disaster program includes orientation and ongoing training and drills for all personnel in all procedures so that each employee promptly and correctly carries out his assigned role in case of a disaster.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 53 FR 12015, Apr. 12, 1988. Redesignated and amended at 60 FR 2326-2327, 2329, Jan. 9, 1995]

**§ 485.729 Condition of participation:  
Program evaluation.**

The organization has procedures that provide for a systematic evaluation of its total program to ensure appropriate utilization of services and to determine whether the organization's policies are followed in providing services to patients through employees or under arrangements with others.

(a) *Standard: Clinical-record review.* A sample of active and closed clinical records is reviewed quarterly by the appropriate health professionals to ensure that established policies are followed in providing services.

(b) *Standard: Annual statistical evaluation.* An evaluation is conducted annually of statistical data such as number of different patients treated, number of patient visits, condition on admission



and discharge, number of new patients, number of patients by diagnosis(es), sources of referral, number and cost of units of service by treatment given, and total staff days or work hours by discipline.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326-2327, 2329, Jan. 9, 1995]

## PART 486—CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS

### Subpart A—General Provisions

Sec.

486.1 Basis and scope.

### Subpart B—[Reserved]

### Subpart C—Conditions for Coverage: Portable X-Ray Services

- 486.100 Condition for coverage: Compliance with Federal, State, and local laws and regulations.
- 486.102 Condition for coverage: Supervision by a qualified physician.
- 486.104 Condition for coverage: Qualifications, orientation, and health of technical personnel.
- 486.106 Condition for coverage: Referral for service and preservation of records.
- 486.108 Condition for coverage: Safety standards.
- 486.110 Condition for coverage: Inspection of equipment.

### Subpart D—Conditions for Coverage: Outpatient Physical Therapy Services Furnished by Physical Therapists in Independent Practice

- 486.150 Condition for coverage: General requirements.
- 486.151 Condition for coverage: Supervision.
- 486.153 Condition for coverage: Compliance with Federal, State, and local laws.
- 486.155 Condition for coverage: Plan of care.
- 486.157 Condition for coverage: Physical therapy services.
- 486.159 Condition for coverage: Coordination of services with other organizations, agencies, or individuals.
- 486.161 Condition for coverage: Clinical records.
- 486.163 Condition for coverage—physical environment.

### Subparts E-F—[Reserved]

### Subpart G—Conditions for Coverage: Organ Procurement Organizations

- 486.301 Basis and scope.
- 486.302 Definitions.
- 486.304 General requirements.
- 486.306 Qualifications for designation as an OPO.
- 486.307 OPO service area size designation and documentation requirements.
- 486.308 Condition: Participation in organ procurement and transplantation network.
- 486.310 Condition: Adherence to performance standards.
- 486.314 Effect of failure to meet requirements.
- 486.316 Designation of one OPO for each service area.
- 486.318 Changes in ownership or service area.
- 486.325 Termination of agreement with HCFA.

### APPENDIX A TO SUBPART G OF PART 486—GUIDELINES FOR PREVENTING TRANSMISSION OF HUMAN IMMUNODEFICIENCY VIRUS THROUGH TRANSPLANTATION OF HUMAN TISSUE AND ORGANS

AUTHORITY: Sections 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

### Subpart A—General Provisions

#### § 486.1 Basis and scope.

(a) *Statutory basis.* This part is based on the following sections of the Act:

1138(b)—for coverage of organ procurement services.

1861(p)—for coverage of outpatient physical therapy services furnished by physical therapists in independent practice.

1861(s) (3), (15), and (17)—for coverage of portable X-ray services.

(b) *Scope.* (1) This part sets forth the conditions for coverage of certain specialized services that are furnished by suppliers and that are not specified in other portions of this chapter.

(2) The conditions for coverage of other specialized services furnished by suppliers are set forth in the following regulations which, unless otherwise indicated, are part of this chapter:

(i) Ambulatory surgical center (ASC) services—Part 416.

(ii) Ambulance services—Part 410, subpart B.